

EG-Konformitätserklärung/EC Declaration of Conformity

gemäß Anhang III der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998
as per Annex III of Directive 98/79/EC of the European Parliaments and Council of 27 October 1998

Hersteller/Manufacturer: Roche Diagnostics GmbH

Adresse/Address: Sandhofer Strasse 116
D-68305 Mannheim

Die Roche Diagnostics GmbH erklärt, dass das Produkt/die Produktfamilie
Roche Diagnostics GmbH declares that the product/the product line

Produktname/Product name: **Folate III CalSet**

Art.-Nr./Cat. No.: **07560001190**

Beschreibung/Description: Folate III CalSet wird zur Kalibration des quantitativen Elecsys
Folate III Tests an Elecsys und **cobas e** Immunoassay-Systemen
verwendet.
*Folate III CalSet is used for calibrating the quantitative Elecsys
Folate III assay on the Elecsys and cobas e immunoassay
analyzers.*

auf das/die sich diese Erklärung bezieht, den Forderungen der EG-Richtlinie 98/79/EG des Rates vom
27. Oktober 1998 (bzw. seine Umsetzung in nationales Recht der Mitgliedsstaaten in welchen das Produkt
vermarktet werden soll) über In-vitro-Diagnostika entspricht.
*to which this declaration relates fulfils the requirements of EC Directive 98/79/EC of the Council of 27 October
1998 (and its relevant transposition into the national laws of the Member States in which the device is intended
to be placed on the market) concerning in-vitro diagnostic devices.*

Mannheim, 26 June 2015

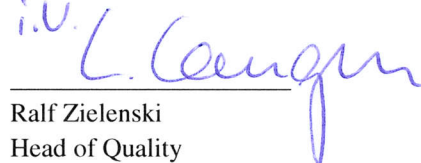
Roche Diagnostics GmbH

ppa./on behalf of the company



Dr. Peter Martin
Senior Director Global Regulatory Affairs
Roche Professional Diagnostics

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